

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

)	
ZYDUS PHARMACEUTICALS (USA) INC.,)	
)	
Plaintiff,)	
)	Civil Action No. _____
v.)	
)	
NOVARTIS PHARMACEUTICALS CORP. and)	
NOVARTIS AG,)	
)	
)	
Defendants.)	
_____)	

COMPLAINT FOR DECLARATORY JUDGMENT

Plaintiff Zydus Pharmaceuticals (USA) Inc. (“Plaintiff” or “Zydus”), by its counsel, respectfully submits this Complaint for Declaratory Judgment against Defendants Novartis Pharmaceuticals Corp. and Novartis AG (collectively “Novartis” or “Defendants”) seeking a declaration that Zydus’s deferiasirox tablets, 180 mg, described in Zydus’s Abbreviated New Drug Application (“ANDA”) No. 211383 (“Zydus’s ANDA”) do not and will not infringe any valid claim of U.S. Patent No. 9,283,209 (“the ’209 patent”). Zydus brings this suit to obtain patent certainty under 21 U.S.C. § 355(j)(5)(C)(i)(I) and to obtain final U.S. Food and Drug Administration (“FDA”) approval to engage in the commercial manufacture, use, importation, offer for sale, and sale of Zydus’s deferiasirox tablets, 180 mg, at the earliest possible date pursuant to 21 U.S.C. § 355(j)(5)(D)(i)(I). Zydus alleges as follows:

THE PARTIES

1. Plaintiff Zydus is a corporation organized and existing under the laws of the State of New Jersey, having a principal place of business at 73 Route 31 North, Pennington, New Jersey 08534.

2. On information and belief, Defendant Novartis Pharmaceuticals Corp. is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business in East Hanover, New Jersey.

3. On information and belief, Defendant Novartis Pharmaceuticals Corp. is the holder of New Drug Application (“NDA”) No. 206910 for JADENU®.

4. On information and belief, Defendant Novartis AG is a corporation organized and existing under the laws of Switzerland and has its principal place of business in Basel, Switzerland and is the corporate parent of Novartis Pharmaceuticals Corp.

5. Based on publicly available information, Novartis AG is the owner and assignee of record with the United States Patent and Trademark Office (“USPTO”) of the ’209 patent.

6. On information and belief, Novartis currently markets deferasirox 90 mg, 180 mg, and 360 mg tablets under the tradename JADENU®, pursuant to FDA’s approval of NDA No. 206910.

JURISDICTION AND VENUE

7. This is a Complaint for a declaratory judgment that Zydus’s deferasirox tablets, 180 mg, described in Zydus’s ANDA do not and will not infringe any valid or enforceable claims of the ’209 patent and which arises under the patent laws of the United States, 35 U.S.C. §§ 1 *et seq.*, the Hatch-Waxman Act, 21 U.S.C. §§ 355(j) *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

8. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a), because this action involves substantial claims arising under the United States Patent Act (35 U.S.C. §§ 1 *et seq.*), the Declaratory Judgment Act (28 U.S.C. §§ 2201 and 2202), 21 U.S.C. § 355(j)(5)(C), and 35 U.S.C. § 271(e)(5).

9. An actual controversy exists between Zydus and Novartis by virtue of Novartis's listing of the '209 patent in the Orange Book for JADENU® (deferasirox) tablets, Zydus's filing of Zydus's ANDA with the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j), for deferasirox tablets, 180 mg, and Novartis's failure to bring suit against Zydus in connection with the filing of Zydus's ANDA.

10. On information and belief, another applicant was the first to file a substantially complete ANDA that identifies JADENU® (deferasirox) tablets, 180 mg, as the reference listed drug and which contains a Paragraph IV certification for the '209 patent. As a result, on information and belief, this other applicant retains eligibility for 180-day marketing exclusivity, which indefinitely blocks approval of any subsequently filed ANDA, including Zydus's ANDA. A final decision of noninfringement or invalidity of the '209 patent is necessary to lift this regulatory block. *See Apotex, Inc. v. Daiichi Sankyo, Inc.*, 781 F.3d 1356, 1368–69 (Fed. Cir. 2015).

11. Zydus has a right to make, use, offer to sell, and sell its products as described in Zydus's ANDA without a license from Novartis.

12. This Court has personal jurisdiction over Novartis Pharmaceuticals Corp. because, on information and belief, Novartis Pharmaceuticals Corp. has a principal place of business in East Hanover, New Jersey and conducts substantial business in, and has regular and systematic contact with, the State of New Jersey, including this District. On information and belief, Novartis

Pharmaceuticals Corp. has purposefully availed itself to this forum by, among other things, making, shipping, using, offering to sell or selling, or causing others to use, offer to sell, or sell, pharmaceutical products in the State of New Jersey and deriving revenue from such activities.

13. On information and belief, Novartis Pharmaceuticals Corp. has sued for patent infringement in this District, and has therefore availed itself to this forum, in at least the following cases: *Novartis Pharmaceuticals Corporation v. Actavis, Inc.*, Civ. No. 15-8978 (D.N.J. Dec. 31, 2015); *Novartis Pharmaceuticals Corporation v. Aurobindo Pharma Ltd.*, Civ. No. 15-4427 (D.N.J. June 25, 2015); *Novartis Pharmaceuticals Corporation v. Sagent Pharmaceuticals, Inc.*, Civ. No. 14-7556 (D.N.J. Dec. 3, 2014); *Novartis Pharmaceuticals Corporation v. Dr. Reddy's Laboratories, Ltd.*, Civ. No. 15-7964 (D.N.J. Nov. 6, 2015).

14. This Court has personal jurisdiction over Novartis AG based on, *inter alia*, Novartis AG's systemic and continuous contacts with New Jersey, including this District. Upon information and belief, Novartis AG has conducted and continues to conduct business directly or through, *inter alia*, its subsidiaries, agents, and alter egos, including Novartis Pharmaceuticals Corp., in this District. On information and belief, Novartis AG has purposefully availed itself to this forum by, among other things, making, shipping, using, offering to sell or selling, or causing others to use, offer to sell, or sell, pharmaceutical products in the State of New Jersey and deriving revenue from such activities.

15. On information and belief, Novartis AG has sued for patent infringement in this District, and has therefore availed itself to this forum, in at least the following cases: *Novartis AG v. Apotex Inc.*, Civ. No. 09-5614 (D.N.J. Nov. 3, 2009); *Novartis AG v. Aurobindo Pharma Ltd.*, Civ. No. 17-389 (D.N.J. Jan 19, 2017); *Novartis AG v. HEC Pharm. Co., Ltd.*, Civ. No. 15-1647

(D.N.J. Mar. 5, 2015); *Novartis AG v. Actavis, Inc.*, Civ. No. 14-7849 (D.N.J. Dec. 17, 2014); *Novartis AG v. Teva Pharmaceuticals USA, Inc.*, Civ. No. 11-2289 (D.N.J. Apr. 21, 2011).

16. Novartis AG has also consented to personal jurisdiction in this District in other actions involving generic versions of JADENU® and the '209 patent. *See Piramal HealthCare UK Ltd. v. Novartis AG and Novartis Pharm. Corp.*, No. 19-12651, D.I. 12-1 at 52, Exhibit G, ¶ 3, July 8, 2019 Email From Tim Cook (D.N.J. filed July 22, 2019) (“Novartis AG has not contested personal jurisdiction in the District of New Jersey to the extent it is properly served.”).

17. This Court also has personal jurisdiction over Novartis AG because the requirements of Federal Rule of Civil Procedure 4(k)(2) are met as (a) Zydus’s claims arise under federal law, (b) Novartis AG is a foreign corporation (to the extent Novartis AG asserts that it is not subject to personal jurisdiction in the courts of any state), and (c) Novartis AG has sufficient contacts with the United States as a whole, including but not limited to, contacts with the United States through Novartis AG’s subsidiaries, agents, and alter egos, including Novartis Pharmaceuticals Corp., directing the manufacture, importation, offer for sale, and/or sale of pharmaceutical products that are distributed throughout the United States, applying for and obtaining patents in the United States, and litigating cases in United States courts. *See Novartis AG v. Apotex Inc.*, Civ. No. 09-5614 PGS, 2011 WL 691594 (D.N.J. Jan. 24, 2011); *Novartis AG v. HEC Pharm Co., Ltd.*, Civ. No. 15-00151 (D. Del. Feb 11, 2015).

18. Venue is proper in this Court pursuant to 28 U.S.C. § 1391.

HATCH-WAXMAN ACT OVERVIEW

19. In 1984, Congress passed the Drug Price Competition and Patent Term Restoration Act, commonly referred to as the Hatch-Waxman Act. *See* 21 U.S.C. § 355 and 35 U.S.C. §§ 156 and 271(e). The Hatch-Waxman Act was intended to encourage generic drug competition while leaving intact incentives for research and development of new drugs by “branded” drug companies.

See H.R. Rep No. 98-857, pt. 1 at 14-15 (1984). The Hatch-Waxman Act was designed to stem the rising cost of prescription drugs by bringing less expensive generic drugs to market faster.

20. A company seeking FDA approval of a new drug must submit an NDA to FDA. See 21 U.S.C. § 355. A brand name drug sponsor must also inform FDA of every patent that claims the “drug” or “method of using [the] drug” for which a claim of patent infringement could reasonably be asserted against unlicensed manufacture, use, or sale of that drug product. See 21 U.S.C. § 355(b)(1); 21 U.S.C. § 355(c)(2); 21 C.F.R. § 314.53(b), (c)(2). Upon approval of the NDA, FDA publishes a listing of patent information for the approved drug in FDA’s *Approved Drug Products with Therapeutic Equivalence Evaluations*, commonly referred to as the Orange Book. See 21 U.S.C. § 355(b)(1). The new FDA-approved drug is known as the “reference listed drug.”

21. The Hatch-Waxman Act provides a streamlined process for approving generic drugs. Before marketing a generic version of an FDA-approved drug, a generic drug manufacturer must submit an ANDA to FDA. An ANDA is “abbreviated” because applicants are generally not required to include the extensive preclinical and clinical data that must be included in an NDA for a brand-name drug. Instead, ANDA applicants can rely on the NDA’s preclinical and clinical data if the proposed generic product is “bioequivalent” to the corresponding reference listed drug. See 21 U.S.C. § 355(j)(4)(F).

22. An ANDA must also contain one of four certifications for each patent listed in the Orange Book: (i) that there are no patents listed in the Orange Book; (ii) that any listed patent has expired; (iii) that the patent will expire before the generic manufacturer is seeking to market its generic product; or (iv) that the patent is invalid, unenforceable or will not be infringed by the manufacture, use or sale of the generic drug for which the ANDA is submitted. See 21 U.S.C.

§ 355(j)(2)(A)(vii)(I)-(IV); 21 C.F.R. § 314.94(a)(12). The last of these is commonly referred to as a “Paragraph IV certification.”

23. An applicant submitting an ANDA containing a Paragraph IV certification must provide formal written notice (*i.e.*, a “Notice Letter”) informing both the patent holder and the NDA holder of its Paragraph IV certification. *See* 21 U.S.C. § 355(j)(2)(B)(i).

24. The Hatch-Waxman Act encourages prompt resolution of patent disputes by authorizing a patent owner to sue an ANDA applicant for patent infringement if a Paragraph IV certification has been made. *See* 35 U.S.C. § 271(e)(2). By statute, if the patent owner brings suit within 45 days of receiving notice of the Paragraph IV certification, the suit will trigger an automatic statutory 30-month stay of FDA approval of the ANDA to allow parties time to adjudicate the merits of the infringement action before the generic company launches its product. *See* 21 U.S.C. § 355(j)(5)(B)(iii).

25. To encourage prompt generic entry, the Hatch-Waxman Act grants the first applicant to file a substantially complete ANDA containing a Paragraph IV certification to an Orange Book-listed patent (“first filer”) a 180-day period of marketing exclusivity that begins only upon the date it begins commercial marketing of its generic drug product.

26. To curb abuses of the 180-day exclusivity by patent owners and first filers, where the 180-day exclusivity is used to block subsequent ANDA filers from obtaining approval of their respective ANDAs, Congress enacted the Medicare Modernization Amendments (“MMA”) to the Hatch-Waxman Act, which provide various conditions under which a first filer would forfeit 180-day eligibility. *See* 21 U.S.C. § 355(j)(5)(D).

27. If the first filer does not commercially market the generic drug product and none of the MMA forfeiture provisions are triggered, the first filer's 180-day exclusivity period can be delayed indefinitely, ultimately blocking final FDA approval of subsequent ANDAs.

28. Under the MMA's forfeiture provisions, a first filer forfeits 180-day eligibility if the first filer fails to market its ANDA product within 75 days of a final court decision obtained by a subsequent ANDA filer as to the patent(s) that confer exclusivity on the first filer, provided that the subsequent ANDA filer has obtained tentative approval of its ANDA. 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb); *Daiichi Sankyo*, 781 F.3d at 1369. As part of this remedy, the Hatch-Waxman Act allows an ANDA applicant to bring a declaratory judgment action asserting that its ANDA product will not infringe any valid claim of any relevant Orange-Book listed patent if (1) neither the patent owner nor the NDA holder brought an action for infringement of the patent within 45 days of receiving the ANDA applicant's Notice Letter and (2) the ANDA applicant's Notice Letter included an offer of confidential access to the ANDA. 21 U.S.C. § 355(j)(5)(C)(i)(I)(aa)-(cc).

29. By authorizing declaratory judgment actions under these circumstances, Congress intended that full generic competition would not be delayed indefinitely by the first filer's 180-day exclusivity. A declaratory judgment action by a subsequent ANDA applicant can result in a final court decision that triggers forfeiture of the first-filer's 180-day exclusivity under 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(AA), thereby clearing the way for final approval of a subsequent-filer's ANDA.

30. Congress explained the need for civil actions to obtain patent certainty:

[W]hen generic applicants are blocked by a first generic applicant's 180-day exclusivity, the brand drug company could choose not to sue those other generic applicants so as to delay a final court decision that could ... force the first generic to market. In ... these ... circumstances, generic applicants

must be able to seek a resolution of disputes involving all patents listed in the Orange Book with respect to the drug.

Caraco Pharm. Labs., Ltd. v. Forest Labs., Inc., 527 F.3d 1278, 1285 (Fed. Cir. 2008) (quoting 149 Cong. Rec. S15885 (Nov. 25, 2003) (remarks of Sen. Kennedy, ranking member of U.S. Senate Committee on Health, Education, Labor, and Pensions)).

**ZYDUS'S DEFERASIROX TABLETS, 180 MG,
ARE BLOCKED FROM FINAL APPROVAL**

1. Novartis listed the '209 Patent in FDA's Orange Book

31. On information and belief, Novartis Pharmaceuticals Corp. is the holder of NDA No. 206910 for JADENU[®] (deferasirox) tablets, 90 mg, 180 mg, and 360 mg (the "JADENU[®] NDA").

32. Novartis requested that the FDA list the '209 patent in the Orange Book in connection with the JADENU[®] NDA as a patent to which "a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug" product containing 90 mg, 180 mg, and 360 mg deferasirox in a tablet. 21 U.S.C. § 355(b)(1), (c)(2). In doing so, Novartis has demonstrated its intent to enforce the '209 patent.

33. The '209 patent, entitled "Oral Formulations of Deferasirox," issued on March 15, 2016. The '209 patent names Indrajit Ghosh and Jia-Ai Zhang as inventors and identifies Novartis AG as the assignee of record. A true and correct copy of the '209 patent is attached hereto as Exhibit A.

34. According to the Orange Book, the '209 patent does not expire until November 21, 2034.

2. The First Filer for Deferasirox Tablets, 180 mg

35. Separate 180-day exclusivity periods are available for each strength of the same drug product because each strength is a distinct drug product. *See Apotex, Inc. v. Shalala*, 53 F. Supp. 2d 454, 456 (D.D.C. 1999) (citing FDA conclusion that “each strength of drug product is a separately listed drug.”) Thus, an ANDA applicant must obtain forfeiture for each drug strength.

36. FDA maintains the identity of ANDA first filer(s) as confidential. However, FDA publishes the date of submission of the first substantially complete ANDA containing a Paragraph IV certification for each drug. For JADENU®, FDA identifies October 19, 2015 as the date of submission of the first substantially complete ANDA containing a Paragraph IV certification for the 90 mg and 360 mg strengths.

37. Upon information and belief, the first filer for deferiasirox tablets, 90 mg and 360 mg, has withdrawn its Paragraph IV certification and therefore has forfeited any 180-day exclusivity to which it may have been entitled. *See Stipulation and Order of Dismissal Without Prejudice at ¶ 2, Novartis Pharm. Corp. v. Actavis, Inc.*, C.A. No. 15-1219-RGA (D. Del. ordered Sept. 18, 2017), ECF No. 123.

38. The '209 patent was listed in the Orange Book for the JADENU® NDA after October 19, 2015.

39. The FDA identifies the date of submission of the first substantially complete ANDA containing a Paragraph IV certification for deferiasirox tablets, 180 mg, as April 21, 2016. On information and belief, this ANDA applicant holds eligibility for 180-day marketing exclusivity that prevents all subsequently filed ANDAs (including Zydus's ANDA) for deferiasirox tablets, 180 mg, from receiving final FDA approval.

3. Zydus Applies for FDA Approval of Deferasirox Tablets, 90 mg, 180 mg, and 360 mg

40. On December 13, 2017, Zydus submitted Zydus's ANDA under 21 U.S.C. § 355(j), seeking FDA approval to engage in the commercial manufacture, use, importation, offer for sale, and sale of deferasirox tablets, 90 mg, 180 mg, and 360 mg ("Zydus's deferasirox ANDA products"). Zydus's ANDA contains a Paragraph IV certification that the '209 patent will not be infringed by the manufacture, use, or sale of Zydus's deferasirox ANDA products. Zydus submitted its ANDA *after* April 21, 2016, and therefore is a "subsequent filer" with respect to deferasirox tablets, 180 mg. As a subsequent filer, Zydus is blocked from obtaining final FDA approval to engage in the commercial manufacture, use, importation, offer for sale, and sale of Zydus's deferasirox tablets, 180 mg, by the first filer's exclusivity.

41. On February 14, 2018, Zydus sent notice to Novartis of Zydus's Paragraph IV certification regarding the '209 patent in Zydus's ANDA and provided an Offer of Confidential Access to its ANDA No. 211383 pursuant to 21 U.S.C. §§ 355(j)(2)(B)(ii) & (iv) ("Zydus's Notice Letter").

42. Novartis received Zydus's Notice Letter on or around February 15, 2018.

43. In its Notice Letter, Zydus provided to Novartis a detailed factual and legal basis for Zydus's Paragraph IV certification to the '209 patent, explaining why the '209 patent would not be infringed by Zydus's deferasirox tablets, 90 mg, 180 mg, and 360 mg.

44. On March 26, 2018, Zydus provided to Novartis a copy of Zydus's ANDA, which contains detailed information about the composition and manufacture of Zydus's deferasirox tablets, 180 mg, to enable Novartis to assess whether to bring a suit for patent infringement.

45. Novartis had a statutory right to bring suit against Zydus if it believed that Zydus's deferasirox tablets, 180 mg, infringed the '209 patent, but Novartis, after reviewing Zydus's ANDA, chose not to file suit. 21 U.S.C. § 355(j)(5)(B)(iii).

46. As Novartis did not sue Zydus within the 45-day period following receipt of Zydus's Notice Letter, Zydus brings this declaratory judgment action for patent certainty and to obtain a final decision to remove the block on final FDA approval so that Zydus can engage in the commercial manufacture, use, importation, offer for sale, and sale of Zydus's deferasirox tablets, 180 mg. 21 U.S.C. § 355(j)(5)(C)(i)(I)(aa)-(cc).

4. Zydus's Obtains FDA's Final Approval for Zydus's Deferasirox Tablets, 90 mg and 360 mg, But FDA's Final Approval of Zydus's Deferasirox Tablets, 180 mg, Is Blocked

47. Zydus has received FDA's final approval, and commenced the commercial manufacture, use, importation, offer for sale, and sale of, its deferasirox tablets, 90 mg and 360 mg.

48. Zydus has received FDA's tentative approval of its deferasirox tablets, 180 mg, but FDA has not granted final approval for Zydus's deferasirox tablets, 180 mg, because of the first filer's exclusivity based on the '209 patent.

49. As a consequence, absent a judgment from this Court declaring that Zydus's deferasirox tablets, 180 mg, do not infringe any valid claim of the '209 patent, Zydus is unable to obtain FDA's final approval of Zydus's deferasirox tablets, 180 mg, indefinitely, injuring Zydus by blocking Zydus from commencing the commercial manufacture, use, importation, offer for sale, and sale of, its deferasirox tablets, 180 mg, and depriving it of sales revenue. *See* 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb).

AN ARTICLE III CASE OR CONTROVERSY EXISTS

50. There is an actual and ongoing controversy between Zydus and Novartis with respect to infringement of the '209 patent that can be resolved by a declaratory judgment from this Court. A judgment from this Court that Zydus's deferasirox tablets, 180 mg, do not infringe any valid claim of the '209 patent is necessary to trigger forfeiture of the first filer's exclusivity, as Congress intended under 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb), with respect to Zydus's deferasirox tablets, 180 mg, allowing Zydus to obtain FDA's final approval and engage in the commercial manufacture, use, importation, offer for sale, and sale of its deferasirox tablets, 180 mg, at the earliest possible date, and enhancing generic competition.

51. The present dispute between Zydus and Novartis satisfies the three-part framework for determining whether an action presents a justiciable Article III controversy: (1) the plaintiffs have standing; (2) the issues are ripe for adjudication; and (3) the case is not rendered moot. *Caraco*, 527 F.3d at 1291.

52. Zydus is injured in fact by the listing of the '209 patent in FDA's Orange Book. The '209 patent confers 180-day exclusivity eligibility for the first filer, which serves to preclude Zydus from obtaining FDA's final approval and engaging in the commercial manufacture, use, importation, offer for sale, and sale of, Zydus's deferasirox tablets, 180 mg, at the earliest possible date. Zydus's injury is unique in the Hatch-Waxman context as compared to ordinary infringement action: "Ordinarily, a potential competitor in other fields is legally free to market its product in the face of an adversely-held patent. In contrast, under the Hatch-Waxman Act, an ANDA filer . . . is not legally free to enter the market [without FDA approval]." *Id.* (brackets in original). Novartis's listing of the '209 patent in the Orange Book therefore creates a bottleneck to Zydus obtaining FDA's final approval of Zydus's ANDA, causing injury-in-fact to Zydus. *Id.*

53. Zydus's injury is directly traceable to Novartis, not the Hatch-Waxman Act or the FDA regulations. For example, the following facts, each traceable to Novartis, are the reasons for Zydus's injury: (1) Novartis chose not to sue Zydus after receiving a notice of Zydus's Paragraph IV certification, so as to avoid an adverse judgment on the '209 patent; and (2) to date, Novartis has never asserted the '209 patent, so as to avoid an adverse judgment. Novartis's actions are precisely the sort of "gaming" the system that the civil action to obtain a patent certainty was designed to prevent.

54. But for Novartis's attempts to avoid litigating the infringement of the '209 patent, FDA's final approval of Zydus's deferasirox tablets, 180 mg, would not be independently and artificially delayed. But for Novartis's actions to delay resolution of the infringement of the '209 patent, Zydus's ability to obtain FDA's final approval and engage in the commercial manufacture, use, importation, offer for sale, and sale of Zydus's deferasirox tablets, 180 mg, would not be delayed by the first filer's 180-day exclusivity.

55. Zydus's injury is redressable by a judgment of noninfringement or invalidity of the '209 patent from this Court that will activate forfeiture of the first filer's exclusivity period as Congress intended, allowing Zydus to obtain FDA's final approval and engage in the commercial manufacture, use, importation, offer for sale, and sale of Zydus's deferasirox tablets, 180 mg, at the earliest possible date and obtain patent certainty.

56. Accordingly, there is an actual, substantial, and continuing justiciable case and controversy between Zydus and Novartis over which this Court can and should exercise jurisdiction and declare the rights of the parties. *Caraco*, 527 F.3d at 1291.

57. Whether an action is "ripe" requires an evaluation of "both the fitness of the issues for judicial decision and the hardship to the parties of withholding court consideration." *Id.* at

1294-95. Zydus satisfies both prongs for ripeness. First, additional factual development would not advance the district court's ability to decide Zydus's action because Zydus's ANDA which has been submitted to FDA for approval has all the necessary information to determine whether Zydus's deferasirox tablets, 180 mg, infringe the '209 patent. Second, Zydus will not be able to obtain patent certainty to market its deferasirox tablets, 180 mg, at the earliest possible date without a declaratory judgment, a hardship that creates the potential for substantial lost revenue.

58. The mootness doctrine requires that the parties must maintain a requisite personal stake. Zydus's deferasirox tablets, 180 mg, are being blocked from the market indefinitely. Only a judgment from this Court—either through adjudication or by consent decree—is necessary to alleviate the harm to Zydus and the public.

COUNT ONE

(Declaratory Judgment of Noninfringement of U.S. Patent No. 9,283,209)

59. Zydus hereby incorporates by reference its allegations contained in paragraphs 1 through 58 of this Complaint as though fully set forth herein.

60. Novartis caused the '209 patent to be listed in the Orange Book as covering its JADENU® (deferasirox) tablets, 180 mg.

61. Zydus filed an ANDA with a Paragraph IV certification stating the '209 patent is not and will not be infringed by the marketing of Zydus's deferasirox tablets, 180 mg.

62. Zydus intends to engage in the commercial manufacture, use, importation, offer for sale, and sale of its deferasirox tablets, 180 mg, as described in ANDA No. 211383, once it obtains final FDA approval, which is currently blocked by a first filer's 180-day exclusivity.

63. There is a real, actual, and continuing justiciable case and controversy between Zydus and Novartis regarding the infringement of the '209 patent by Zydus's deferasirox tablets, 180 mg, as described in ANDA No. 211383.

64. No valid and enforceable claim of the '209 patent will be infringed by the manufacture, use, offer for sale, sale, and/or importation of Zydus's deferasirox tablets, 180 mg, as described in ANDA No. 211383.

65. Accordingly, Zydus seeks and is entitled to a judicial declaration that the manufacture, use, offer for sale, sale, and/or importation of Zydus's deferasirox tablets, 180 mg, as described in ANDA No. 211383, do not and will not infringe, directly or indirectly, any valid claim of the '209 patent.

PRAYER FOR RELIEF

WHEREFORE, Zydus prays for a declaratory judgment against Novartis as follows:

A. Judgment against Novartis declaring that the '209 patent is not and will not be infringed by Zydus's deferasirox tablets, 180 mg, as described in ANDA No. 211383;

B. Declaring the manufacture, marketing, use, offer for sale, sale, and/or importation of Zydus's deferasirox tablets, 180 mg, do not infringe and will not, if marketed, infringe or induce or contribute to the infringement of any valid claim of the '209 patent;

C. Awarding Zydus its costs, expenses and reasonable attorneys' fees pursuant to 35 U.S.C. § 285; and

D. Awarding Zydus such other and further relief as the Court deems just and reasonable.

Dated: December 10, 2019

/s/ Theodora McCormick
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CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 11.2

Pursuant to Local Civil Rule 11.2, the undersigned hereby certifies that the patent at issue in this action, U.S. Patent No. 9,283,209, is the subject of the following actions pending before this Court:

Piramal Healthcare UK Ltd. v. Novartis Pharm. Corp., Case No. 2:19-cv-12651

Cipla Ltd. v. Novartis AG, Case No. 2:19-cv-20810

Alembic Pharm., Ltd. v. Novartis Pharm. Corp., Case No. 2:19-cv-20890

The undersigned further certifies that the matter in controversy is not the subject of any other action pending in any court, or of any pending arbitration or administrative proceeding.

Dated: December 10, 2019

/s/ Theodora McCormick
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CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 201.1

Pursuant to Local Civil Rule 201.1, the undersigned hereby certifies that this action involves complex legal issues and the legal issues predominate over the factual issues; therefore, the matter is not appropriate for compulsory arbitration.

Dated: December 10, 2019

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